REMARKS/ARGUMENTS

Claims Status

Claims 7, 9, 11, 13, 19, 20 and 22-25 are pending. Claims 1-6 were previously canceled without prejudice and claims 8, 10, 12, 14-18 and 21 are currently canceled without prejudice. Claims 7, 11, 13, 19 and 20 are currently amended. Claims 22-25 are added. Amended claim 7 now includes the subject matter of claim 8 and finds support for "having acidic residues in the molecule" in the specification: page 5, lines 7-8. Claims 11, 13, 19 and 20 are amended for grammatical purposes and to improve readability. New claim 22 finds support in the specification: page 5, lines 28-30. New claim 23 finds support in the specification: page 5, lines 7-23. New claim 24 finds support in the specification: example 1 (page 10, line 26, to page 11, line 18). New claim 25 finds support in the specification: examples 2-2 to 2-4 (page 12, line 13, to page 14, line 4). No new matter is believed to have been added.

§112 Rejections

Claims 7-21 are rejected under 35 U.S.C. §112, 1st paragraph, for lack of sufficient written description for the following claimed elements: "basic physiologically active substance", "one or more enteric polymers", "one or more electrolytes" and "sparingly-soluble binder". Applicants respectfully traverse these rejections.

At the outset it should be noted that all claims referring to "sparingly-soluble binder" have been canceled. With respect to "basic physiologically active substance", Applicants note that the specification explains that the "'basic physiologically active substance' can be applied to the present invention as long as it exhibits basicity in general meaning, and is not particularly limited" (page 4, lines 27-29). In addition, Applicants note that "tamsulosin

hydrochloride" is exemplified throughout the specification and specifically recited in claim 9, and independent claims 24 and 25.

With respect to "one or more enteric polymers", Applicants note that the specification explains that the "'enteric polymer' used in the present invention refers to a polymer having acidic residues in the molecule thereof to maintain the form of the preparation in the stomach in a strongly acidic environment but being dissolved in the small intestine in a weakly acidic to weakly basic environment to disintegrate the preparation to release the physiologically active substance" (page 5, lines 7-12). In addition, the specification continues by giving a list of examples of such enteric polymers (page 5, lines 13-23). Applicants note that some of these specific enteric polymers, including those exemplified in the examples, are specifically recited in claim 23 and independent claims 24 and 25.

With respect to "one or more electrolytes", Applicants note that the specification explains that the "'electrolyte' is not particularly limited as long as it is a medically acceptable inorganic electrolyte which can be highly dissolved in an aqueous solvent such as digestive fluids to release ions" (page 5, lines 24-27). In addition, the specification continues by noting preferred electrolytes (alkali metal salts and alkaline earth metal salts) and by naming and exemplifying specific electrolytes (sodium chloride, potassium chloride, magnesium chloride and calcium chloride) (page 5, lines 27-30). Applicants also note that these specific electrolytes, including those exemplified in the examples, are specifically recited in claim 22 and independent claims 24 and 25.

Accordingly, since such statements (as quoted above) clearly convey with reasonable clarity to those skilled in the art that Applicants were in possession of the invention as now claimed, the written description requirement as explained in MPEP 2163.02 ("to satisfy the written description requirement, an applicant must convey with reasonable clarity to those

skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed") has been met.

In addition, as the Office has not provided evidence that there is substantial variation within any of the claimed genera such that a broader variation of exemplified species is needed, the species exemplified in the specification are presumed to be an adequate representative number of species such that the genera are adequately described and again convey with reasonable clarity to those skilled in the art that which Applicants claim.

Accordingly, Applicants request withdrawal of these rejections.

Fukui Rejection

Claim 1 (presumably was intended to state claim "7") is rejected under 35 U.S.C. §102(b) as anticipated by *Fukui* (US 4,772,475). Applicants respectfully traverse this rejection.

At the outset it should be noted that the subject matter of claim 8 is not subject to this rejection and independent claim 7 now includes the subject matter of claim 8. Accordingly, this rejection is believed to have been overcome.

Nonetheless, Applicants submit that *Fukui* does not anticipate the claimed invention for the following reasons. First, *Fukui* does not disclose a single pharmaceutical embodiment comprising *all* three components *as claimed*: a basic physiologically active substance (e.g., tamsulosin hydrochloride), one or more enteric polymers having acidic residues in the molecule thereof (e.g., hydroxypropylmethyl cellulose phthalate and/or methacrylic acid / ethyl acrylate copolymer), *and one or more alkali metal salts and/or alkaline earth metal salts*. Most notably, and as the Office has recognized (Office Action, page 4, last paragraph), *Fukui* discloses the use of magnesium stearate and/or calcium stearate. The Office has equated these stearates to Applicants' "one or more electrolytes"; however this is inaccurate.

As quoted above in the §112 Rejections section, the claimed electrolytes are "highly dissolved in an aqueous solvent". Magnesium stearate and calcium stearate are known to be insoluble in water/aqueous solvents.

Additionally, Applicants' own specification distinguishes *Fukui* from the claimed invention (as the corresponding Japanese Examined Patent Publication No. Hei 7-72129) (page 2, lines 18-23; page 6, lines 12-25; Reference Example 1 at page 9, line 13, to page 10, line 24). More specifically, the specification describes the following with respect to *Fukui*: "the electrolyte in the publication ("metal alkyl halide or earth metal alkyl halide" in the publication) is ... one for merely preventing the release of the physiologically active substance, and not recognized as one for improving the releasability of the physiologically active substance in the intestine as disclosed in the present invention" (page 6, lines 18-25). Furthermore, Reference Example 1 was prepared according to *Fukui* (i.e., a pharmaceutical preparation having tamsulosin hydrochloride, crystalline cellulose, and enteric polymer mixed uniformly therein) and showed a low dissolution rate until the addition of sodium chloride caused the active substance to be "increased all at once."

In contrast, the claimed invention comprising tamsulosin hydrochloride, enteric polymer(s) having acidic residues and electrolyte(s) selected among alkali metal salts and alkaline earth metal salts, provides for an improved release of the basic pharmaceutical preparation (page 11, lines 16-19). As examples 2-1 to 2-4 show, "it was made evident that the basic substance releasability of the preparation not containing electrolyte (preparation 2-1) was suppressed, but the substance releasability of the preparations containing electrolyte in any one of the layers was significantly improved" (page 13, line 30, to page 14, line 4).

Accordingly, not only does *Fukui* not disclose a single embodiment containing all of the claimed elements, but *Fukui's* preparations (see again Reference Example 1) provide for suppressed release of the active substance whereas the claimed invention provides for

improved/progressed release of the active substance. As such, *Fukui* does not anticipate Applicants' claims and Applicants request withdrawal of this rejection.

Platteeuw Rejection

Claims 7-21 are rejected under 35 U.S.C. §102(b) as anticipated by *Platteeuw* (WO 03/039530). Applicants respectfully traverse this rejection.

First, *Platteeuw* does not disclose a single pharmaceutical embodiment comprising *all* three components *as claimed*: a basic physiologically active substance (e.g., tamsulosin hydrochloride), one or more enteric polymers having acidic residues in the molecule thereof (e.g., hydroxypropylmethyl cellulose phthalate and/or methacrylic acid / ethyl acrylate copolymer), *and one or more alkali metal salts and/or alkaline earth metal salts*. Most notably, and as the Office has recognized (Office Action, page 5, last paragraph), *Platteeuw* discloses the use of calcium phosphate. The Office has equated calcium phosphate to Applicants' "one or more electrolytes"; however this is inaccurate. As quoted above in the §112 Rejections section, the claimed electrolytes are "highly dissolved in an aqueous solvent". Applicants provide herewith a section of the Merck Index (11th Edition) that shows that dicalcium phosphate (the compound used in example 1 of *Platteeuw*) is insoluble in water. Accordingly, *Platteeuw* does not disclose all of the recited elements of the claimed composition (see independent claims 7, 24 and 25) and thus can not be considered anticipatory. Therefore, Applicants request withdrawal of this rejection.

Obviousness

In addition to the above remarks with respect to a lack of anticipation of the claimed invention in view of *Fukui* and *Platteeuw*, Applicants offer the following additional remarks with respect to potential obviousness.

Pharmaceutical preparations containing enteric polymers having acidic residues typically do not disintegrate in the strong acidic condition of the stomach, but do disintegrate in the small intestine and consequently release the active substance in the small intestine. However, the release of a *basic* physiologically active substance is typically significantly hindered by the enteric polymer, even in the small intestine.

As a solution to this hinderance, Applicants have discovered that the release of basic active substances is significantly improved when an electrolyte having high solubility in water, such as an alkali metal salt and/or an alkaline earth metal salt, are included in the preparation. What's more is that the preparation containing the electrolyte still does not disintegrate in the strong acidic condition of the stomach. In contrast, *Fukui* and *Platteeuw* are not able to obtain such superior effects.

Conclusion

For the reasons discussed above, Applicants submit that all now-pending claims are in condition for allowance. Applicants respectfully request the withdrawal of the rejections and passage of this case to issue.

Respectfully submitted,

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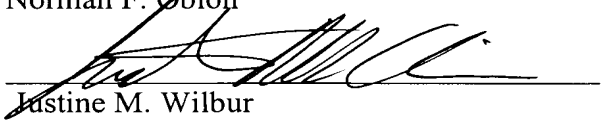

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